JUL 17 2009

K091296

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

Submitter: Pierre Landau, PhD
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Contact Person: Same as submitter

Date of Summary: April 10, 2009

Trade Name: Polytel® GMA (Glucose Meter Accessory), models PWR-08-06, PWR-08-07, PWR-08-09

Common Name: Accessory to Blood Glucose Meter

Classification: no: NBW

A. Predicate Device:
The Polytel® GMA is substantially equivalent to the PWR-08-03 manufactured by Polymap Wireless and the Think Positive (t+) diabetes management system, manufactured by e-San, Ltd. UK.

B.Device Description:

The Polytel® GMA is a telemedicine device that uses Bluetooth technology to transmit data from a glucose monitor to compatible access points such as a personal computer, standalone device or cellular phone with Bluetooth capability. It is connected to the glucose meter by a phono jack and uses short-range low power wireless transmission (Bluetooth v2.0) to send the data to Bluetooth compatible access point. The unit is battery powered.

C.Intended use and indications for use:

The Polytel GMA (models PWR-08-06, PWR-08-07, and PWR-08-09) are remote communications link devices intended to be used to wirelessly transmit glucose meter readings from a compatible Blood Glucose Monitor to a compatible cellular phone, such as the Nokia N73 or access point, such as the Polytel® APT. The receiving device, in turn, sends the readings to the healthcare provider in another location. The device does

not send any real-time alarms. Clinical judgment and experience are required to check and interpret the information delivered.

D. Substantial Equivalence Summary

The Polytel GMA has the same fundamental scientific technology and intended use as the predicate devices (K070559 and K061328). .

E. Technological Characteristics

The Polytel GMA has technological characteristics that are very similar to those of the predicate devices as all use Bluetooth technology. All these devices are battery powered. Each device uses the same frequency band (2.402 to 2.480 GHz.

F. Testing

The testing consisted of three types: bench testing using Polymap procedures and specifications; field testing under actual use conditions; and, performance standards testing. The results were acceptable

G. Conclusions

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in Sections 513(0)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and guidance documents issued bye the Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Polymap Wireless, LLC
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Tucson, AZ 85711

JUL 17 2009

Re: k091296
Trade Name: Polytel GMA models PWR-08-06, PWR-08-07, and PWR-08-09
Regulation Number: 21 CFR § 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW
Dated: April 29, 2009
Received: May 4, 2009

Dear Dr. Landau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091296

Device Name: Polytel® GMA

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device

510(k) K091296